Exactech®

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K012251

JUL 3 1 2001

Exactech® Optetrak ™ Total Knee System
Stem Extensions – Additional Sizes

510(k) Summary of Safety and Effectiveness
Special 510(k)

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: **(352) - 377 - 1140**
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FDA Establishment Number 1038671

Contact: **Robert Paxson**
Director of Engineering & Development

Date: **June 22, 2001**

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Classifications / Proprietary Names:

Classification Name:	Prosthesis, knee, patellofemorotibial, semi-contrained, cemented, polymer/metal polymer
Trade / Proprietary Model Names:	Optetrak Total Knee System Stem Extensions – Additional Sizes
Product Code:	JWH
C.F.R. Section:	888.3560
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) Number
Optetrak Total Knee	Exactech	#K933610
Optetrak Total Knee	Exactech	#K954208
Nexgen	Zimmer	----------
Maxim	Biomet	----------
Durcon Total Stabilizer	Howmedica	----------

Device Information:

INDICATIONS

The OPTETRAK® Total Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

CAUTION: For cemented use only in the USA.

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CONTRAINDICATIONS

The OPTETRAK® Total Knee Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, and in patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and in patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

DEVICE DESCRIPTION

Like the original Optetrak stem extensions, the proposed Optetrak Straight Stem Extension additional sizes are composed of Titanium alloy (ASTM F-1472). The proposed stem extensions have the same Morse taper call out and flute that the existing stem extensions offer. The design incorporates the same design features as the predicate Optetrak stem extensions over new lengths and diameters to create a complete range of sizes for the surgeon. The proposed Straight Stem Extension Line Extensions are fully compatible with the existing Optetrak Tibial Trapezoid trays (#K933610) and the Constrained Condlyar Femoral Component and bushing (#K954208).

PACKAGING MATERIALS

Packaging Materials	
Material	**Composition**
Vacuum Bag	High Barrier – 3 Mil, 75 gauge Nylon with EVOH 2.25 Polyethylene
Polymer Bags	3 Mil Polyethylene
Inner/Outer Pouches	48GAPET/.002LDPE
Pouch Seals	1073B Uncoated Tyvek®
Box	Heavy weight cardboard
Outer Shrink-Wrap	Clear, Light-Weight Plastic
Shipping Cartons	Heavy-weight Corrugated Cardboard

STERILIZATION INFORMATION

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): 10^{-6}

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PERFORMANCE DATA

The design assurance reviews for the proposed products did not indicate the need for additional testing since the parts were so comparable to the existing Exactech stem extensions and no new failure modes were identified.

According to analytical analysis the proposed stem extension components showed that the stem extension strength was independent of length and diameter. Therefore, the proposed stem extensions should have the similar clinical results to the existing Exactech straight stem extensions.

We conclude that the new Optetrak Stem Extensions are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Mr. Robert Paxson
Director of Engineering & Development
Exactech, Inc.
2320 N.W. 66th Court
Gainsville, Florida 32653

Re: K012251
Trade Name: Optetrak Total Knee System
Regulatory Class: II
Regulation Number: 888.3560
Product Code: JWH
Dated: July 17, 2001
Received: July 18, 2001

Dear Dr. Paxson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak Total Knee System
Straight Stem Extensions – Additional Sizes

Indications for Use

510(k) Number: K012251

Device Name: Optetrak Total Knee System
Straight Stem Extensions

INDICATIONS
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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012251

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____